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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/646,294

08/22/2003

Bjarne Due Larsen

50412/021002

9323

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04/05/2007

CLARK & ELBING LLP  
101 FEDERAL STREET  
BOSTON, MA 02110

EXAMINER

TELLER, ROY R

ART UNIT

PAPER NUMBER

1654

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/05/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/646,294

Applicant(s)

LARSEN ET AL.

Examiner

Roy Teller

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 93-109 is/are pending in the application.
- 4a) Of the above claim(s) 98 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 103, 104, 106 and 107 is/are allowed.
- 6) ☒ Claim(s) 93-97, 99-102, 105, 108-109 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 1/29/04.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

This office action is in response to the election, received 1/8/07, in which applicant elected the species: hydroxyacetyl-Asn-Tyr-NH<sub>2</sub>, without traverse.

A search was conducted for the elected species, hydroxyacetyl-Asn-Tyr-NH<sub>2</sub>. This species was found to be free of the prior art. The search was extended to the following species: hydroxyacetyl-Asn-Tyr-OH; Ac-hydroxyacetyl-Asn-Tyr-NH<sub>2</sub>; Ac-hydroxyacetyl-Asn-Tyr-OH; and hydroxyacetyl-Asn-Tyr-OH. These species were found to be free of the prior art. Claims 103, 104, 106 and 107 read on the species corresponding to hydroxyacetyl-Asn-Tyr-NH<sub>2</sub>; hydroxyacetyl-Asn-Tyr-OH; Ac-hydroxyacetyl-Asn-Tyr-NH<sub>2</sub>; Ac-hydroxyacetyl-Asn-Tyr-OH; and hydroxyacetyl-Asn-Tyr-OH. Claim 98 is withdrawn as being drawn to a non-elected species. Claim 98 was withdrawn because, in accordance with the MPEP, "should the examiner determine that the elected species is allowable, the examination of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior search, however, will not be extended unnecessarily to cover all nonelected species".

Claims 93-97, and 99-109 are under examination. Claim 98 is withdrawn as being drawn to a nonelected species.

### ***Information Disclosure Statement***

The information disclosure statement, received 1/29/04, is acknowledged. A signed copy is enclosed hereto.

***Claim Objections***

Claims 103, 104, 106 and 107 are objected to for depending upon a rejected claim.

Appropriate action is requested.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 93-97, 99-100, 105, 108, and 109 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 93 recites the compound R1-X1-X2-X3-R2. The claim is vague and indefinite because R2 is not defined in any way. Clarification is requested.

Claim 93 recites X1 and X2 as 0. The claim is unclear as to whether 0 is an oxygen or a zero. If 0 is zero, then is zero an active agent. Clarification is requested.

All other claims depend directly or indirectly from the rejected claim and are, therefore, also rejected under 35 USC 112, second paragraph for the reasons set forth above.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 93-97, 100-102, 105 and 108-109 are rejected under 35 U.S.C. 102(a) as being anticipated by Scialdone et al (USPN 6,815,426).

The instant invention is drawn to a compound represented by Formula VIII: R1-X1-X2-X3-R2 wherein X1 is 0, Ala, Gly, B-Ala, Tyr, D-Tyr, Asp, or hydroxyacetyl; X2 is 0, Ala-Gly-T4c-Pro, Ala-Sar-Hyp-Pro, Ala-6ring-, Ala-Asn, D-Asn-D-Ala, D-Asn, gamma-Abu, Gly, Ala, D-Ala, B-Ala, Pamh, Asn, or hydroxycetyl; X3 is Tyr, D-Tyr, Gly, Pamb, or Phe; R1 is H or Ac; and pharmaceutically acceptable salts thereof, provided that X1 and x2 are not both 0.

Scialdone et al. discloses a tripeptide of formula aa1-aa2-aa3 having a first amino acid (aa1), a second amino acid (aa2), and a third amino acid (aa3) wherein said first amino acid is selected from the group consisting of Ser, Thr, Ala, Phe, Tyr, Cys, Gly, Leu, Lys, Pro, Arg, Gln, Glu, Asp, Asn, His, Met, Ile, Trp, and Val; said second amino acid is selected from the group consisting of Asn, Ala, Gly, Asp, Glu, and Gln; said third amino acid is selected from the group consisting of Ser, Thr, Ala, Phe, Tyr, Cys, Gly, Leu, Lys, Pro, Arg, Gln, Glu, Asp, Asn, His, Met, Ile, Trp, and Val. See, i.e., for example, column 25-26, claim 1. This reads on the limitations of instant claims 93-97 and 100. Scialdone discloses a pharmaceutical composition comprising the tripeptide of claim 1. See, i.e., for example, column 26, claim 8. This reads on the

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limitations of instant claim 105. Scialdone discloses a method for administering the tripeptide via an oral route. See, i.e., for example, column 27, claim 20. this reads on the limitations of instant claims 108 and 109. Scialdone discloses a compound, comprising capped tripeptide of the formula aa1-aa2-aa3, having a first amino acid (aa1), a second amino acid (aa2), and a third amino acid (aa3) wherein said first amino acid is selected from the group consisting of Ser, Thr, Ala, Phe, Tyr, Cys, Gly, Leu, Lys, Pro, Arg, Gln, Glu, Asp, Asn, His, Met, Ile, Trp, and Val; said second amino acid is selected from the group consisting of Asn, Ala, Gly, Asp, Glu, and Gln; said third amino acid is selected from the group consisting of Ser, Thr, Ala, Phe, Tyr, Cys, Gly, Leu, Lys, Pro, Arg, Gln, Glu, Asp, Asn, His, Met, Ile, Trp, Val and wherein said third amino acid is capped with a compound selected from the group consisting of NH<sub>2</sub>, OH and NHR, wherein R is selected from the group consisting of alkyl and aryl. See, i.e., for example, column 28, claim 23. This reads on the limitations of instant claims 93, 101 and 102.

Therefore, the cited reference is deemed to anticipate the instant claims above.

### ***Conclusion***

Claims 93-97, 99-102, 105, 108 and 109 are rejected. Claims 103, 104, 106 and 107 are drawn to allowable material.

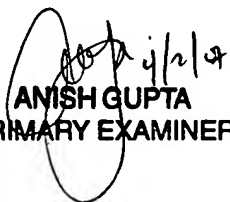
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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**ANISH GUPTA**  
**PRIMARY EXAMINER**